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PROGRESS REPORT

September 1 through September 30, 1997

OFFICE OF NAVAL RESEARCH GRANT NO:

N00014-95-1-0055

National Marrow Donor Program®
3433 Broadway Street N.E.
Suite 500
Minneapolis, MN 55413

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PROGRESS REPORT FOR OFFICE OF NAVAL RESEARCH

GRANT NO: N00014-95-1-0055

(As Modified through P00001, A00003)

This periodic progress report covers activities supported by Grant #N00014-95-1-0055, as modified, from September 1 through September 31, 1997. This Grant was due to expire on September 30, 1996. Amendment A00002 extended it through December 31, 1996. Amendment A00003 extended it through September 30, 1997. As only 12 budgeted line items will have activity, this report is limited to those items.

I. PROJECT DESCRIPTION

A. Specific Aims

During this period, the National Marrow Donor Program® (NMDP) used grant funds to support activities directed toward the following goals:

1. Enhance an already effective system which rapidly identifies and tracks the availability of matched donors for patients requiring marrow transplants.
2. Increase the total number and racial diversity of the NMDP's volunteer donor file and provide HLA-DR typing on as many donors as possible in an effort to reduce patient search time and costs.
3. Perform HLA typing of the donor/recipient samples stored in the NMDP's research sample repository, and compare the detailed molecular typing results with patient outcome data to determine the correlation between post-transplant outcome and degree of HLA match.

B. Budgeted Categories

1. **\$5,224,188 Scientific Studies of Allele-Specific Typing of Donor\Recipient Samples.**
2. **\$0 NMDP HLA Match Vs. Outcome Research (Reallocated)**
3. **\$16,124,798 Histocompatibility Laboratories for DNA HLA-DR Typing**
4. **\$24,000 Histocompatibility Laboratories for HLA-A, B & DR Typing**
5. **\$0 NMDP Staff Immunogeneticist (Reallocated)**
6. **\$553,625 Repository**
7. **\$600,000 Feasibility for Confirmatory Class I DNA Testing**

8. **\$0 Contract Laboratory for Reference/Pre-Test Cells (Reallocated)**
9. **\$100,000 Class I Sequencing Database**
10. **\$853,620 Donor Center Hardware/Software**
11. **\$498,023 Facilitation of Rapid Communication with Foreign Registries**
12. **\$12,717 Probability of A, B, DR Identical Matches**
13. **\$200,000 Revision of Search Algorithm**
14. **\$209,316 Data Management for the International Consortium on the Effects of Radiation/Studies of Effects of Exposure to Ionizing Radiation**
15. **\$34,680 HR/HW Search**
16. **\$0 Resolution of Discrepant HLA Typing on Donors (Reallocated)**
17. **\$67,545 Donor HLA Override Modifications**
18. **\$0 Enhancements to BMDW Processing (Reallocated)**
19. **\$0 Cord Blood Repository Software (Reallocated)**
20. **\$0 Transplant Center Software (Reallocated)**
21. **\$0 Modify Repository Software (Reallocated)**
22. **\$11,425,000 Minority HLA-A, B Typing**
23. **\$67,153 National Minority Campaigns**
24. **\$232,925 Pilot Recruitment/Retention Program**
25. **\$6,428,157 Community HLA-A, B Matching Funds**
26. **\$5,859 Donor Center Waiting Lists**
27. **\$135,000 Physician Histocompatibility and Transplant Center Coordinator Education**
28. **\$963,540 Registry Wide Newsletter**

- 29. \$0 Transplant and Collection Center Newsletter (Reallocated)
- 30. \$3,898 Physician Education
- 31. \$15,109 Patient Education
- 32. \$0 NMDP Speaker Support Materials (Reallocated)
- 33. \$579,003 Targeted Group Awareness and Education Activities
- 34. \$535,818 Integrated Communications for Targeted Campaigns
- 35. \$0 Phase II National Public Service Campaign (Reallocated)
- 36. \$96,663 Long Term Blood Storage Alternative Investigations
- 37. \$315,625 Program Administration
- 38. \$293,738 Alternative Blood Products Software

II. RESULTS BY CATEGORY

A. HLA Typing And Research

1. Scientific Studies of Allele-Specific Typing of Donor\Recipient Samples

This project's primary objective is to determine the impact of HLA matching, defined by the highest resolution of molecular typing possible, on transplant outcome. The project was initiated with funding from Navy Grant N00014-93-1-0658 and continues under funding from this grant. There are three phases to this study. Phase I continues the allele level Class II typing on the donor-recipient samples stored in the NMDP's repository at Irwin Memorial Blood Center; Phase II continues the allele-level Class I typing on the donor-recipient samples; and Phase III involves data analysis and transplant outcome correlation.

Phase I

The nine laboratories involved in this phase of the project have now completed the typings of the first 1,302 donor-recipient pairs funded under Navy grant N00014-93-1-0658. Upon evaluation of competitive bids, 6 laboratories were selected to continue participation in this project. The new contracts and typing of 1,000 new donor recipient paired samples began in December 1996. The NMDP began to receive

typing results in January 1997. Results reported to date are detailed in Attachment 2A.

Phase II

The five Laboratories involved in this phase of the project have now completed the primary typing of the first 750 pairs. Resolution of identified typing discrepancies and non-amplifiable samples is in progress. New contract amendments were issued on February 12 to type the next 1,500 pairs, and additional samples have been sent to the laboratories. Results reported to date are detailed in Attachment 2B.

The NMDP will be responsible for the management of the data generated by the Class I and II typing laboratories. Software and programming to manage the data and to make the necessary comparison was completed January 1996.

3. Histocompatibility Laboratories for DNA HLA-DR Typing

In February 1992, a DNA pilot project was implemented to test the feasibility of using DNA technology, specifically Polymerase Chain Reaction (PCR) Sequence Specific Oligonucleotide Probe (SSOP) typing to identify the Class II antigens at the HLA-DR and DQ loci. An additional focus of the pilot project was to institute a quality control system which would monitor the performance of the laboratories and establish an accuracy standard for PCR-SSOP typing. The pilot project successfully demonstrated that prospective collection of HLA-DR samples for storage and later typing by DNA contract laboratories was an efficient option for prospective HLA-DR typing of large numbers of volunteer donors as well as for patient-directed typing. In addition, the blind quality control program has shown that molecular HLA-DR typing can be performed at high volume and low cost and still be highly accurate (less than a 2% error rate overall). The efforts of the pilot project were funded under Navy grant N00014-91-J-1895.

Based on the success of the DNA pilot project, the program was expanded (under funding provided through Navy grants N00014-92-J-1551 and N00014-93-1-0658) to include two DNA repositories, 16 contract DNA typing laboratories and all the NMDP donor centers. The design of the DNA project remained virtually identical to that of the pilot project and continues to include ongoing quality control. Funding for these typings was provided through this Navy grant beginning on March 1, 1995. Prior to that time, Navy Grant N00014-93-1-0658 funded the typings for this project. Attachment 3A details the activities of these laboratories.

6. Repository

The NMDP's two DNA repositories (American Red Cross National Headquarters and Children's Hospital of Pittsburgh) continued to receive samples from virtually all of the NMDP's donor centers. Approximately 90%-95% of all newly recruited donors have samples submitted to one of the two NMDP DNA repositories. Currently, repository services provided by the Children's Hospital of Pittsburgh are funded separately. The activity of the two repositories during the report period is detailed in Attachment 3B.

7. Feasibility for Confirmatory Class I DNA Testing

The technology of molecular HLA typing for identification of Class I HLA types has progressed rapidly in the past few years. Although the technology is not as advanced as in Class II HLA typing, it has progressed to the point where antigen-level typing can be performed by molecular means for the HLA-A and B loci.

The feasibility of developing a network of labs to perform DNA-based HLA-A, B typing, the impact on existing procedures and practices at the transplant centers and DNA repositories, and the costs associated with developing this network would be determined and used to evaluate whether network-wide implementation is possible. The benefit of utilizing molecular Class I typing lies in the ability to perform a very accurate, detailed molecular typing on a stored sample, to confirm a questionable result or to implement confirmatory typing while the donor is completing other parts of the search process, such as the information session or physical exam. Either scenario would result in a shortened search process, because fewer discrepant samples would be identified in later stages of the search process. The ability to conduct confirmatory typing in parallel with other donor procedures would significantly shorten the search process, saving lives in those cases when the patient has little time to spare. During this report period 4,585 typing results were reported to the NMDP.

B. Electronic Communication

1. Donor Center Hardware/Software

The conversion of STAR LinkTM to all domestic donor centers using DMAT has been completed. As of the end of July 1997, 87 donor centers were successfully converted to STAR Link.

2. Facilitation of Rapid Communication with Foreign Registries

The NMDP is working in cooperation with foreign registries to provide international data exchange and to streamline international searches. The STAR[®] system has been installed and is currently operating at the

Australian Bone Marrow Donor Registry (ABMDR) in Australia. As of September 1997, the upgrade of ABMDR's version of STAR application has completed testing and implementation into the production environment has been successful. A duplicate of ABMDR's system has been set up at the NMDP to provide a test environment for the upgrade.

The NMDP preliminary searches are sent electronically on a daily basis to the Anthony Nolan Bone Marrow Trust in England, who then returns a file of search results. A similar interface has been designed, developed and tested for France Greffe de Moelle (FGM). The NMDP began electronically sending preliminary searches to the FGM in July of 1996.

4. Revision of Search Algorithm

Although the STAR[®] system stores the DNA typing data for both donors and recipients, the current matching algorithm evaluates the match grade based upon serologic equivalent typing results. The NMDP Histocompatibility Committee addressed the need to revise the algorithm to incorporate molecular-based matching at its November 6, 1995, meeting. A working group of histocompatibility experts and transplant center physicians has been assigned to define the matching criteria. All the funding available for this project in N00014-95-1-0055 has been expended; however, effort continues under the Cooperative Agreement.

10. Cord Blood Repository Software

This category has been reallocated to \$0. Effort on this project was delayed due to completion of other cord blood phases. These funds were reallocated in March 1996 to fund the Alternative Blood Products Software.

C. Donor Services Activities

3. Pilot Recruitment/Retention Programs

In 1993, the NMDP requested Navy funds to continue minority focused recruitment efforts after the targeted campaigns were completed. The goal was to develop models for each racial/ethnic group that would maximize the numbers of donors recruited onto the registry and also improve retention of these donors when they were contacted for further testing on behalf of a patient.

The NMDP seeks to build on previous programs funded by the Navy with special attention to those recruitment strategies and programs that have proven to be most successful and appear to provide the greatest opportunity for replication in other areas.

A Request for Proposal (RFP) was let in the spring of 1995 to community based organizations and donor centers in selected geographic areas. The response was very low and determined not to be competitive.

The Navy was asked to allow the NMDP to redefine the use of the funds for this program for the following:

- Provide an opportunity for existing NMDP recruitment groups (8) that focus on minority recruitment to receive one recruitment staff position. The RFP was let in June 1996 with a response deadline of July 19, 1996. Four (4) recruitment groups were awarded subcontracts for a Coordinator for Minority Public Education/Awareness, based on proposals submitted and reviewed through September 30, 1997.
- Provide staff support for the American Indian/Alaska Native initiative, especially for health professional education about unrelated marrow transplantation.

Remaining funds were reallocated out of this line item for community matching typings.

D. Public Education and Awareness

4. Physician Education

The third annual Transplant Center Coordinator Spring Meeting was held on April 14-15 at the Doubletree Hotel in Tucson, AZ. Approximately 90 centers attended, representing over 75% of U.S. transplant centers. The agenda included a 90 minute session on Search Strategies, which focused on different approaches to donor searches when the patient has an unusual or hard-to-type HLA type. Attention was also paid to submission and completion of the NMDP recipient data forms, as well as the NMDP's future plans to incorporate DNA-based Class I and Class II typings into the search algorithm. Overall presentation ratings were either "good" or "excellent".

7. Targeted Group Awareness and Education Activities

Communication & Education staff continue to create new opportunities to generate visibility in the media and help our local centers increase the potential success of events and activities designed to raise awareness of the need for volunteers, particularly minorities, to join the Registry.

8. Integrated Communications for Targeted Campaigns

The NMDP uses communications firms with cultural experience and resources specific to each targeted audience. The expertise of C&E and the firms enables development of culturally sensitive, campaign-specific materials in languages key to our audiences. These materials are tested among representative groups for cultural sensitivity and effectiveness.

E. Long Term Blood Storage Alternative Investigations

A contract (#6030) with Coriell Institute for Medical Research was issued on March 1, 1995, to evaluate alternative methodologies of long term whole blood storage and to compare them with the current protocol of freezing whole blood in 1 ml aliquots. Based on less than satisfactory performance, this contract was terminated for convenience of the NMDP on November 7, 1995. An amount of \$6,989 was made to Coriell as complete payment for services performed. An RFQ was sent in May 1997 to the DNA-based HLA-A,B and HLA-DR typing contract laboratories to provide typing services for this study. Samples were distributed to the participating laboratories on July 8, 1997. The baseline testing results have been received and are being analyzed. The six month testing results are due January 7, 1998.

F. Program Administration

During this period no funds were expended from this category to cover the salary, office rental, and related expenses of the Administrator of Navy Funded Programs. Attachment 1 reflects all approved reallocations.

III. SUMMARY

Navy grant # N00014-95-1-0055 continues to support the NMDP projects which decrease the time and expense required for patients to find compatible unrelated donors, while funding research designed to increase understanding of the role of HLA matching on patient outcome post-transplant. Many of the activities described in this report represent continuations of successful projects implemented previously.

ATTACHMENT 1

\$45,000,000 NAVY GRANT SUMMARY OF ACTIVITIES

NAVY GRANT N00014-95-1-0055 REALLOCATIONS REPORT

Category	Original Grant Budget	Added by Modification P00001	TOTAL MODIFIED GRANT AMOUNT	Reallocation *											Total Reallocated Grant Amount
				#1 02/14/95	#2 06/06/95	#3 03/06/96	#4 05/10/96	#5 06/5/96	#6 09/06/96 (Verbally apptd. 8/96)	#7 08/28/96	#8 08/28/96	#9 12/19/96	#10 4/15/97	#11 7/21/97	
1 Scientific Studies of Allele-Specific Typing of Donors	\$3,100,000	\$1,450,000	\$4,550,000												\$5,224,188
2 NMDP HLA Match Vs. Outcome Research	\$500,000	\$0	\$500,000												\$0
3 Histocompatibility Laboratories for DNA HLA-DR Ty	\$6,700,000	\$5,300,000	\$12,000,000												\$16,124,798
4 Histocompatibility Laboratories for HLA-A, B & DR	\$2,300,000	\$500,000	\$2,800,000												\$24,000
5 NMDP Staff Immunogeneticist	\$200,000	\$700,000	\$400,000												\$553,625
6 Repository		\$300,000	\$700,000												\$600,000
7 Feasibility for Confirmatory Class I DNA Typing	\$0	\$300,000	\$300,000												\$0
8 Contract Laboratory for Reference/Pre-Test Cells	\$0	\$100,000	\$100,000												\$100,000
9 Class I Sequencing Database	\$0	\$100,000	\$100,000												\$0
10 Donor Center Hardware/Software	\$1,000,000	\$1,000,000	\$2,000,000												\$853,620
11 Facilitation of Rapid Communication with Foreign Re	\$500,000	\$0	\$500,000												\$498,023
12 Probability of A, B, DR Identical Matches	\$50,000	\$0	\$50,000												\$12,717
13 Revision of Search Algorithm	\$200,000	\$0	\$200,000												\$200,000
14 Data Management for the International Consortium on	\$250,000	\$150,000	\$400,000												\$209,316
15 HLA/HLA Search	\$0	\$0	\$0												\$34,680
16 Resolution of Discrepant HLA Typing on Donors	\$0	\$75,000	\$75,000												\$0
17 Donor HLA Overlap Modifications	\$0	\$75,000	\$75,000												\$67,545
18 Enhancements to BMDW Processing	\$0	\$100,000	\$100,000												\$0
19 Curt Blood Repository Software	\$0	\$150,000	\$150,000												\$0
20 Transplant Center Software	\$0	\$100,000	\$100,000												\$0
21 Modity Repository Software	\$0	\$75,000	\$75,000												\$0
22 Minority HLA-A, B Typing	\$4,400,000	\$5,750,000	\$10,150,000												\$11,425,000
23 National Minority Campaigns	\$250,000	\$750,000	\$1,000,000												\$67,153
24 Pilot Recruitment/Retention Program	\$500,000	\$500,000	\$1,500,000												\$232,925
25 Community HLA-A, B Matching Panels	\$2,100,000	\$2,300,000	\$4,400,000												\$6,428,157
26 Donor Center Waiting Lists	\$450,000	\$103,000	\$553,000												\$5,859
27 Physician Histocompatibility and Transplant Center C	\$100,000	\$160,000	\$260,000												\$155,000
28 Registry Wide Newsletter	\$400,000	\$650,000	\$1,050,000												\$903,540
29 Transplant and Collection Center Newsletter	\$20,000	\$0	\$20,000												\$0
30 Physician Education	\$30,000	\$0	\$30,000												\$3,898
31 Patient Education	\$30,000	\$25,000	\$55,000												\$15,109
32 NMDP Speaker Support Materials	\$20,000	\$0	\$20,000												\$0
33 Targeted Group Awareness and Education Activities	\$150,000	\$0	\$150,000												\$579,003
34 Integrated Communications for Targeted Campaigns	\$550,000	\$0	\$550,000												\$535,818
35 Phase II National Public Service Campaign	\$0	\$50,000	\$50,000												\$0
36 Long Term Blood Storage Alternative Investigations	\$300,000	\$0	\$0												\$96,663
37 Program Administration		\$337,000	\$637,000												\$315,625
38 Alternative Blood Products Software	\$24,600,000	\$21,000,000	\$45,600,000	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$293,738

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ATTACHMENT 2

**(A) HIGH RESOLUTION CLASS II DNA
TYPING LABORATORIES**

**(B) HIGH RESOLUTION CLASS I DNA
TYPING LABORATORIES**

CUMULATIVE DISTRIBUTION OF TYPING RESULTS BY LOCUS
HIGH RESOLUTION CLASS II
TOTAL FOR ALL LABORATORIES
September 30, 1997

LOCUS	RQSTD #	RESULTS COMPLETED		RESULTS OPEN		RESULTS PARTLY COMPLETED		RESULTS NOT COMPLETED		RESULTS NO MAKE	
		#	%	#	%	#	%	#	%	#	%
DRB1	8201	7915	96.5	46	0.6	159	1.9	205	2.5	81	1.0
DRB3	5013	4780	95.4	57	1.1	136	2.7	193	3.8	40	0.8
DRB4	4492	4072	90.7	66	1.5	312	6.9	378	8.4	42	0.9
DRB5	2498	2391	95.7	45	1.8	39	1.6	84	3.4	23	0.9
DPA1	7739	7325	94.7	42	0.5	323	4.2	365	4.7	49	0.6
DPB1	7745	7532	97.2	40	0.5	116	1.5	156	2.0	57	0.7
DQA1	8022	7487	93.3	51	0.6	389	4.8	440	5.5	95	1.2
DQB1	8001	7623	95.3	55	0.7	229	2.9	284	3.5	94	1.2
TOTAL	51711	49125	95.0	402	0.8	1703	3.3	2105	4.1	481	0.9

(36,537 Phase I, 15,174 Phase II)

RQSTD = # of IDs that will be typed at a given locus

COMPLETED = # of IDs where 2 valid results have been received

OPEN = # of IDs where no results have been received

PARTLY COMPLETED = # of IDs where 1 valid result has been received but the second result has not been received

NOT COMPLETED = Sum of OPEN and PARTLY COMPLETE

NO MAKE = # of IDs where a no make has been received at one or both alleles

CUMULATIVE DISTRIBUTION OF TYPING RESULTS BY LOCUS
HIGH RESOLUTION CLASS I
TOTAL FOR ALL LABORATORIES
September 30, 1997

LOCUS	RQSTD #	RESULTS COMPLETED		RESULTS OPEN		RESULTS PARTLY COMPLETED		RESULTS NOT COMPLETED		RESULTS NO MAKE	
		#	%	#	%	#	%	#	%	#	%
A	8552	7162	83.7	1405	16.4	131	1.5	1536	18.0	382	4.5
B	8552	5248	61.4	3172	37.1	336	3.9	3508	41.0	44	0.5
C	8552	7490	87.6	1310	15.3	1	0.0	1311	15.3	412	4.8
TOTAL	25656	19900	77.6	5887	22.9	468	1.8	6355	24.8	838	3.3

(9,000 Phase I, 16,656 Phase II)

RQSTD = # of IDs that will be typed at a given locus

COMPLETED = # of IDs where 2 valid results have been received

OPEN = # of IDs where no results have been received

PARTLY COMPLETED = # of IDs where 1 valid result has been received but the second result has not been received

NOT COMPLETED = Sum of OPEN and PARTLY COMPLETE

NO MAKE = # of IDs where a no make has been received at one or both alleles

ATTACHMENT 3

(A) DONOR TYPINGS PERFORMED

(B) DONORS SAMPLES STORED AND SHIPPED

NMDP DNA PROJECT**DONOR TYPINGS PERFORMED****September 1, 1997 - September 30, 1997**

PRIORITY 1	1,953
PRIORITY 2	18,875
PRIORITY 3	8

TOTAL	20,836
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NMDP DNA PROJECT**DONOR SAMPLES STORED****September 1, 1997 - September 30, 1997**

ARC - NATIONAL	13,351
PITTSBURGH	9,244
<hr/>	
TOTAL	22,595

DONOR SAMPLES SHIPPED**September 1, 1997 - September 30, 1997**

ARC - NATIONAL	13,359
PITTSBURGH	13,900
<hr/>	
TOTAL	27,259